Proposed Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group

Summary of Public Comments

GENERAL COMMENTS

- <u>Support for multidisciplinary approach to review</u>: The proposed changes make a great deal of sense and will increase the number of applications submitted and strengthen the review of multi-disciplinary cutting-edge research.
- <u>Improvement over current system</u>: We strongly support the proposed new approach, as it represents a significant improvement over the current system.
- IRG overlaps: The current proposal contains extensive overlaps in technology, methods
 and applications; particularly between SBIB and the proposed Bioengineering Sciences
 and Technologies (BST) IRG. One IRG should focus on biomedical imaging (both basic
 and applied) and computing while the other should focus on surgery and bioengineering.
 Perhaps more importantly, there is also considerable uncertainty concerning the
 boundaries between SBIB and the organ-system and disease IRGs with respect to
 imaging research.
- <u>Benefit of technology</u>: The reorganization will enable researchers to use technology quicker.
- <u>Impact on review of translational research</u>: The formation of SBIB will ensure that translational projects are adequately evaluated.
- Why reorganize? It is difficult to understand the rationale for the proposed restructuring, because it appears that the system is not "broken", but perhaps could be improved.
- <u>Crosscutting areas</u>: We strongly endorse the idea that imaging and bioengineering be considered crosscutting areas.
- Rationale for including surgical sciences: What is the rationale for including surgical sciences with biomedical imaging and bioengineering?
- <u>Different study sections suggested</u>: There should be five surgery and bioengineering study sections focused on: Biomaterials, Intraoperative Surgical Trauma, Wound Healing, Tissue Repair & Regeneration, and Drug Carriers & Delivery Systems.
- <u>Evaluation criteria for SBIB Working Group</u>: Every year the plan should be reviewed to
 determine if study sections should be modified. One criterion is that the number of
 proposals reviewed by each study section should not be greatly different. A second
 criterion is that the expertise of the study section members should be sufficiently diverse
 to review appropriately a variety of methodologies.
- <u>Disease/Organ-oriented study section compatibility with technology</u>: In general, this is a good and needed change. However, there are situations where it is the application of a technology, rather than the creation of new technology, that is at the cutting edge and

sometimes this is best identified and reviewed within a disease- or organ-specific study section.

 <u>Logic of study section design</u>: The proposed study section names are just as confusing as the old ones. Less emphasis should be placed on engineering and more on pathophysiology.

MEDICAL IMAGING

- Review of imaging proposals by organ-system or disease IRGs: The policy of
 determining review venue on the basis of the scientific questions being addressed
 provides great latitude in assigning proposals to IRGs. Specifically, the descriptions of
 the neuroscience study sections contain multiple references to "neuroimaging,"
 "functional imaging," "calcium imaging," "imaging studies," and "imaging." The lines
 between imaging research proposals that are appropriate for review in neuroscience
 study sections and those that should be reviewed in imaging study sections needs to be
 clearer.
- Review of imaging proposals by organ-system or disease IRGs: Moving to a more organ-based system of reviewing medical imaging applications would pose a significant barrier to getting research projects in medical image perception funded, and would affect our ability to understand and improve diagnostic imaging and interpretation.
- Support for a crosscutting approach to imaging: Even though an imaging proposal may
 focus on an organ system, the importance of the research may not be appreciated or
 understood as well by an organ-system review panel, as it would be by an imaging
 review panel.
- Interdisciplinary approach to review is necessary: Even when clinicians are familiar with the field, advice is often sought concerning technical aspects of imaging. Clinical experts may not be the best reviewers of highly technological advances imaging research. The plan to cluster surgical, imaging and bioengineering applications is supported.
- Missing subject area: Evoked-response methodologies should be included as an "imaging" modality because they provide temporal resolution that may not be attainable otherwise.
- <u>Adjustments needed in BCAP</u>: The introductory paragraph should discuss the
 usefulness of cellular and sub-cellular analyses in the molecular characterization of
 these agents. Endogenous contrast mechanisms in MR, and endogenous optical
 contrast should also be included.
- Adjustments needed to BMIT and MI: Because "Image processing" implies only
 reconstruction, it should be re-worded to include "information extraction". Emphasis
 should also be placed on statistical methods to achieve these goals, and there should be
 strong statistical expertise on both BMIT and MI.

 <u>Request for study section</u>: A study section is needed to review studies of new imaging or therapeutic modalities (i.e., FDG - PET for pancreatic cancer, radioimmunotherapy for melanoma, etc.)

MEDICAL INFORMATICS

 Medical Informatics missing from SBIB: Imaging-based medical informatics should be recognized as a unique entity and added to the SBIB IRG. Examples include application of natural language processing to imaging, methods for image summarization (customizable atlases, knowledge extraction from image studies, imaging-based digital libraries, search engines based on content, etc.

BIOENGINEERING

- <u>Support for cross-cutting approach</u>: One of the many problems in reviewing bioengineering and biotechnology proposals would be addressed by this "cross-cutting" IRG. Discipline-based study sections often have difficulty providing adequate expertise or enthusiasm for technology-development applications.
- <u>Clarification needed between IRGs</u>: The distinction between IRG-6's interest in fundamental aspects of cell and tissue engineering and IRG-21's responsibility to review integrated proposals in cell and tissue engineering, is unclear.
- <u>Biomaterials:</u> Biomaterials should be a separate study section; it is the platform technology for all of bioengineering.
- Responsibilities of BSST: Transplantation and cardiothoracic surgery should be included in BSST, especially if it concerns tissue engineering or artificial organs that must be integrated with a clinical approach or that rely on knowledge of transplant immunology.
- Rehabilitation activities: Mixing rehabilitation with the other topics of BSST is either highly innovative or very odd.
- BSST is too broad: BSST should be split into Bioengineering and Surgical Sciences and Bioengineering and Surgical Technology, creating a study sections with a technology thrust and with a scientific thrust.
- <u>BSST is too broad</u>: BSST appears too broad to deal with biomaterials, devices, and tissue engineering. The study section should be split into one covering biomaterials, tissue engineering, and implantable devices and a second covering biomechanics (including cell and tissue mechanics, cardiovascular and transport mechanics, and macro-level mechanics, e.g., prosthesis).
- Change needed in BSST: The comment that proposals studying a specific organ should be reviewed by "organ-specific IRG's" goes counter to the concept that tissue response to a prosthesis or foreign material is a general process, and almost always affects multiple organ systems.

 Overlap with MOSS: The BSST discussion of shared interest should include the Musculoskeletal, Oral and Skin Sciences [MOSS] IRG, specifically the Skeletal Biology and Diseases 2 study section.

SURGERY

- Applaud the creation of three surgical study sections:
- A Surgery IRG: Surgical science is specialized and important enough to warrant an IRG of its own.
- <u>Support a crosscutting approach to peer review:</u> The PSBR Panel recognized a potential for particular research areas to suffer when distributed across many IRGs and indicated that such applications should be clustered. Surgical research is such an area.
- Reorganization is supportive of surgical research: The proposed reorganization acknowledges the strides being made in the surgical sciences and will foster more focused review of surgical topics.
- Organization of study sections is good: A big problem with the present surgery study section is that surgeons, not planning to conduct surgical research, believe that because the work is proposed by a surgeon it should be reviewed by this study section, thus creating an entitlement for surgeons.
- <u>Thanks:</u> These guidelines will foster collaborative relationships with the basic sciences that will move surgical research forward.
- <u>Vascular surgery</u>: There is no study section specifically devoted to issues of peripheral vascular atheroscleotic disease, venous disease and lymphatic diseases. There is no way vascular surgery can compete with trauma, cardiac and transplant surgery.
- <u>Neurosurgery</u>: The description of neurosurgery is appropriate to improve technical surgery. There is a need for research that is not influenced by commercial interests.
- <u>Trauma should have its own IRG</u>: Trauma should have a separate institute, as it is the primary cause of death of those under14-years of age.
- <u>Transplantation perspective</u>: Thanks for maintaining transplantation as a single entity. The current descriptions are satisfactory, however, the topics in SAT could be rearranged under the following themes: inflammation, injury, and anesthesiology.
- <u>Transplant reviews in the new study sections</u>: Systematic biases against certain disciplines are likely to result from their assignment to organ- or disease-specific review panels because of the lack of crosscutting expertise. This is particularly problematic in transplantation research. Sepsis is another area requiring cross-disciplinary expertise for optimal review.
- <u>Clinical perspective</u>: While it is important for applications to be reviewed by scientists knowledgeable in the specific area of study, it is equally important that they be reviewed

by physician/scientists with appropriate clinical expertise. Surgical study sections should review most "surgical" applications.

- Diluting surgery: I am strongly opposed to the addition of radiology to the former Surgery and Bioengineering Study Section. I am also strongly opposed to mixing surgery with other disciplines. This extraordinarily biased effort ignores the contributions of surgeons to the increase in medical knowledge. The boundaries do not encompass truly innovative research that is outside currently accepted concepts and ignores important "niche" research such as blood-synthetic surface interactions or cardioplegia. This "niche research" is extremely important in surgery, but not necessarily important in other disciplines. To force studies of these surgically important problems to go to "boundary encircled study sections" that are not peopled with experts in the subject matter of the application, is unfair. Even if a token surgeon is assigned to the study section, he or she may be totally unaware of the "niche" being addressed. The assault by CSR staff and non-surgical advisors on the surgical study sections is unjustified, wrong, and in some ways betrays the American patient. Surgery "B" is now predominately populated by bioengineers who have little or no understanding of surgery. Few have ever been in the operating room, and none have confronted the problems that surgeons do. Adding radiologists further squeezes the surgeons out chances to have their applications funded. Surgery B should have a slight predominance of surgeons, no radiologists and only engineers who collaborate on various surgically initiated projects. Surgeons should be kept together so that only the best surgeon investigator projects are funded. Diluting surgeons as token representation over a large number of study sections is unfair, unworkable and should not be allowed. The two study sections allotted to surgeons should not be targeted for extinction as this boundary-based reorganization is attempting to do. Adding a hybrid study section with a minority of surgeon members only worsens the problem.
- <u>Alternate proposal for Surgery</u>: There should be three or four study sections dealing with surgery. One should include anesthesiology, trauma and surgical critical care; the second should be involved with bioengineering and surgical sciences and technology; and the third would cover the remainder of surgery and organ transplantation. A strong argument could be made that organ transplantation should have its own study section since it is very specialized and increasing in importance. While these study sections would emphasize surgery, they could also review related topics in basic science.
- Overlaps between SBIB and CVS: The extensive overlaps between study sections in SBIB and those in CVS are not adequately discussed in the guidelines for either IRG. Both transplantation and reperfusion of the heart would be better served if they only went to one study section where there was truly a good fit with the expertise of the members of the study section and a critical mass of reviewers
- Comparison of surgical and radiological approaches: I do not believe that surgical
 approaches, e.g., in the comparison of minimally invasive surgical staging of lung cancer
 with radiologic staging, will be treated fairly by any study section under this
 reorganization.
- <u>Transplantation:</u> Organ-specific study sections should review only those transplantation applications having a very narrow, organ-specific scope. Most transplant applications should be reviewed in one of two transplant-focused study sections, one in SBIB and the

other in Immunology, with complementary, but largely non-overlapping areas of focus. STAS should review applications focused on the technical aspects of transplantation, tissue engineering and regeneration, organ donation, preservation, and allocation, pharmacological immunosuppression and translational research. The proposed Transplantation, Tolerance and Tumor Immunology (TTT) study section in the Immunology IRG should review proposals focused on immunologic aspects of rejection, including strategies for the development of clinical transplantation tolerance, and basic molecular, cellular and mechanistic aspects of allorecognition and the alloimmune response as it pertains to rejection of transplanted organs, tissues, and cells. Moreover, proposals pertaining to the role of major or minor histocompatibility antigens and the development of transplantation tolerance in either experimental or clinical settings, generally would be reviewed in TTT.

- <u>Transplantation</u>: The proposal to create two study sections for transplantation (non-immunological aspects of transplantation to be reviewed in SBIB and those focused on immunological topics to be reviewed in the Immunology IRG) appears to be a logical division of the transplantation research. Since many aspects of transplantation immunology have a commonality with autoimmune diseases and tumor biology, TTT would include a reasonable grouping of topics.
- <u>Support for maintaining the current SAT</u>: SAT currently reviews a diverse set of applications with a well-rounded group of reviewers, and is "vertically" integrated in most areas allowing it to bring expertise from multiple areas. Cross talk also occurs between the different groups.
- Another approach to SAT: SAT could review R01, K, and SBIR applications on the following topics: anesthesiology (including pain management); pulmonary, cardiac and vascular responses to trauma/burn/surgery/physiologic stress and their implications in rehabilitation and PEEP; alterations in metabolism associated with trauma, burn, sepsis, surgical stresses including microsurgery, experimental studies of cardiopulmonary resuscitation, cell signaling/priming/preconditioning; systemic r (including immune functions, hypothalamus-pituitary- adrenal-axis, and gene transfer strategies to promote injury modulation); basic science aspects of cardiovascular surgical sciences, ischemia/reperfusion, formed blood elements-endothelial cell interactions, liver, kidney, GI and lung functions, pharmacologic modulation of trauma/surgical stress (including the impact of gene polymorphisms), studies of the etiology and intervention of multiple organ dysfunction, nutritional/metabolic support of the injured patient; basic science and translational research aspects of surgical critical care and emergency medicine; and experimental studies of wound repair/scarring and tissue regeneration following injury (including studies of neutrophil, endothelial, epithelial and mast cell functions).
- <u>Pain research</u>: The following topics should be included in SAT: mechanisms and management of pain; acute pain; and pain related to surgery, trauma, and burns.
- Overlap between SAT and HBP: Some of the guidelines for SAT are vague, e.g., GI surgery is included in SAT, but cirrhotic hepatocyte growth is not. Should it be reviewed in SAT or in the Digestive Sciences IRG's Hepatobiliary Biology and Pathobiology (HBP) study section?

- <u>SAT overlaps</u>: The list of topics included within SAT is extremely broad, for instance "cell signaling/priming/preconditioning" overlap extensively with nearly every other IRG. Inclusion of ischemia/reperfusion under anesthesiology is inappropriate.
- <u>Sepsis, trauma, etc. should be in SAT</u>: Applications that deal with sepsis, burns and trauma are best reviewed in SAT, not STAS. Surgical critical care often involves anesthesiologists as the intensivists and these applications are better reviewed by SAT. Other areas better reviewed by SAT include inflammation, injury, anesthesia, perioperative care, and sepsis.
- <u>Surgical Critical Care:</u> The rationale for including surgical critical care in STAS is unclear. The major problems of surgical critical care are sepsis and host responses to sepsis and injury. The expertise and focus for these topics would be better represented in SAT. Emergency medicine, on the other hand, is a field that does not substantially overlap with surgery or anesthesiology. However, [surgical] critical care is an inpatient subspecialty involving both surgeons and anesthesiologists.
- <u>Surgical Critical Care:</u> Surgical critical care should be reviewed in SAT; there is a
 natural overlap between "anesthesiology and host responses to sepsis and injury" and
 surgical critical care. Furthermore, surgical critical care providers study "sepsis and
 injury" (included in SAT). On the other hand, there is no common ground between
 transplantation and GI surgery and surgical critical care.
- <u>Name change</u>: In the Surgery, Surgical Critical Care, and Transplantation study section, "Surgical Critical Care" should be changed to "Critical Care Medicine" to reflect the multidisciplinary nature of critical care. Also, the membership should include anesthesiologists.
- Another approach to STAS: STAS could review applications on the following topics: organ, tissue, and cellular transplantation, surgical implications of immunobiology related to tissue typing, organ preservation, and plastic/reconstructive surgery; cadaver tissue transplantation; adjunct therapies to transplantation; pulmonary, cardiac and vascular responses to transplantation and their implications in rehabilitation; clinical aspects of surgical critical care (including cardiopulmonary resuscitation); system-specific aspects of organ or tissue response to surgery (e.g., hepatobiliary, GI, and cardiovascular); and studies that utilize a multi-model approach to clinical correlations.